

**Amendments to the Figures:**

On figure 31, the peak at 1536 should be corrected to be a peak at 1593. A Replacement Sheet is attached showing this correction.

**REMARKS**

Claims 1-97 are pending, with claims 41-54 and 97 subject to examination. The undersigned confirms election of claims directed to Form U, namely claims 41-54, and 97.

Claims 53 and 97 have been provisionally rejected for statutory double patenting. Claim 97 has also been provisionally rejected for nonstatutory double patenting. The Applicants defer this rejection until that time when there is at least one allowable claims.

The Examiner has not rejected any of the claims in view of the prior art. The Applicants thank the Examiner for finding the claims to be free of the prior art. For the reasons set forth below, the Applicants believe that the claims also meet the requirements of 35 U.S.C. §112. If the Examiner believes that a particular amendment would put the claims in condition for allowance, it is requested that the Examiner contact the undersigned with any suggestions.<sup>1</sup>

The Examiner has rejected claim 53 under 35 U.S.C. §112 first paragraph because *inter alia* “while enabling for seeding the solution with form B, does not reasonably provide enablement for seeding with a crystal of any other form of nateglinide.” Claim 53 has now been amended to recite seeding with Form U or B. The seeding of the solution with Form B crystals is illustrated in Example 17 (page 41) and the specification reasonably conveys to one of ordinary skill of art seeding with type U crystals since if seeding with Form B results in Form U, one of ordinary skill in the would immediately discern seeding with Form U to obtain Form U based on the specification. Furthermore, the specification states : “another way of accelerating crystallization is by seeding with a

crystal of the product. . . “ [Page 21, Lines 30-32]. In this case, Form U is “the product” and thus would be used for seeding.

The Office Action has rejected claim 41-49 for lack of enablement under 35 U.S.C. §112, first paragraph. “The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation” *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988).

The office Action cites *In re Mayhew*, 527 F.2d 1229 (C.C.P.A. 1976) in support of its argument that certain “elements of the process such as temperatures at which each individual step is performed, duration of stirring” or “duration of the crystallization” are critical to the practice of the invention but are not include in the claims. In *In re Mayhew*, the Examiner had rejected claims directed to a method for the production of a corrosion-resistant coating on a steel strip. The Examiner rejected some of the claims under 35 U.S.C. §112 for failure to recite any cooling zone, failure to recite the location of the portion of the bath cooled and failure to recite the temperature range of the cooling zone and its function. The court sustained the rejections based on the failure to recite the step of cooling, finding without it, the invention as claimed was wholly inoperative (meaning it simply would not work and could not produce the claimed product).

However, in *In re Mayhew*, the court reversed the rejection of the claims based on failure to recite the temperature range of the cooling zone, finding that “selection of the temperature of the zone would be within the ability of one of ordinary skill in the art attempting to follow the teaching of the specification” and further noted that “[t]he

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<sup>1</sup> The undersigned appreciates the Examiner’s efforts and kindness in trying to set up interviews (which did not take place) on two separate instances.

language employed in a claim must always be analyzed in light of the specification". *In re Mayhew*, 527 F.2d 1229, 1233-34. In this case, Applicant is not missing a step but rather, its claims do not recite certain conditions such as the temperature, and one of ordinary skill in the art based on the specification would be able to select the temperature and other conditions without undue experimentation.

The Office Action rejects claims 51-52 under 35 U.S.C. §112 first paragraph for lack of enablement, again citing *In re Mayhew*. Relying on the Table on page 19-20 of the specification, the Office Action again states that more conditions need to be recited in the claims. This rejection should be withdrawn for the same reasons provided above. Furthermore, the Table recited in the office Action is not relevant to claims 51 and 52 because the claims are directed to crystallization from a single solvent, while the Table is about processes that use a binary mixture of solvent and antisolvent.

The Office Action rejects claims 53-54 under 35 U.S.C. §112 first paragraph for lack of enablement, again citing *In re Mayhew*. The Office Action seeks that the claims include conditions such as temperature and stirring time. This rejection should be withdrawn for the same reasons provided above. As stated above, in that case, the court reversed the rejection of the claims based on failure to recite the temperature range of the cooling zone, finding that "selection of the temperature of the zone would be within the ability of one of ordinary skill in the art attempting to follow the teaching of the specification" and further noted that "[t]he language employed in a claim must always be analyzed in light of the specification". *In re Mayhew*, 527 F.2d 1229, 1234. In this instance the specification provides sufficient guidance to one of ordinary skill of art to carry out the invention without undue experimentation.

The Office Action objects to Figure 31 for having a peak with a lower value(1536) to the left of a peak with a higher value (1537). There was an error in preparation of the formal drawings, and the peak with the lower value should have had a value of 1593. The peak at 1593 is supported in the original figure submitted with the application. The Applicants are submitting a substitute Figure 31 to correct this error.

### **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request allowance of the pending claims. The Examiner is invited to contact the undersigned attorney to discuss any matter concerning this application. No fee is believed to be due for the submission of this response. Should any fees be required, the Commissioner is hereby authorized to charge any fees which may be necessary for consideration of this paper to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

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